

REMARKS/ARGUMENTS

In view of the foregoing amendments and following remarks, favorable reconsideration of the pending claims is respectfully requested.

Amendments to the Specification

Pages 11-13 of the specification have been amended to identify trademarks with all caps as requested by the Examiner.

Status of the Claims

Claims 1-25 are under examination.

Claim 1 has been amended to clarify that the *Bifidobacterium breve* strain was deposited under the number I-2219 with the CNCM (Collection Nationale de Cultures de Microorganismes in Paris, France).

Claims 8 and 9 have been amended to include the recitations as a Markush Group.

Claims 24 and 25 have been amended to replace the term "it" with "the composition".

Claim Objections

Claims 8, 9, 24, and 25 have been objected to by the Examiner. Claims 8 and 9 have been amended to recite a Markush group as noted above. Claims 24 and 25 are not directed to a Markush Group. Please note the use of the alternative term "or" with respect to each possible form of the composition.

Claim 21 has been objected to as being in improper dependent form. Claim 21 is directed to a composition containing the immunomodulatory product and at least one pharmaceutically acceptable carrier; such combination of at least two ingredients of Claims 21 is clearly different than the scope of Claim 20. Applicants respectfully request withdrawal of this objection.

Rejections under 35 USC § 112

Claims 1-25 have been rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled. . It is respectfully submitted that the microorganism in question has been deposited under the Budapest treaty. In this regard, please find attached a statement by Applicants' representative, Timothy Balts, showing that the deposits fully meet the requirements of 37 CFR §§ 1.806-808. In view of this statement, it is respectfully submitted that this rejection has been overcome.

Appl. No.: 10/552,957
Amdt. dated 09/20/2010
Reply to Office action of 05/11/2010

Claim 1 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.
Claim 1 has been amended as suggested by the Examiner to overcome this rejection.

Double Patenting Rejection

Claims 1-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting as being unpatentable over Claim 6 of copending U.S. Patent Application Serial No. 12/167,630. Applicants request that this rejection be held in abeyance until after the Examiner has withdrawn all prior art rejections.

Prior Art Rejections

Claims 1-25 have rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication 2008/0268099 to Blareau, or by U.S. Patent 7,410,653, also to Blareau. Claims 1-25 have rejected under 35 U.S.C. § 102(b) as being anticipated by WO 01/01785 to Blareau. WO 01/01785 is the PCT equivalent U.S. Patent 7,410,653. Applicants respectfully traverse these rejections.

US 2008/0268099 to Blareau describes an immunomodulatory product obtained by the bioconversion of a milk substrate with the aid of *Bifidobacterium breve* strain I-2219. The immunomodulatory product described in Blareau comprises the substrate used to culture the bacteria *Bifidobacterium breve* I-2219 mixed with said *Bifidobacterium breve* I-2219 (Blareau does not teach to remove the bacteria or to extract a specific fraction of the obtained culture broth).

The claimed invention is directed to an immunomodulatory product obtained by the incubation of the same bacteria, *Bifidobacterium breve* I-2219, on an aqueous substrate comprising lactoserum permeate, lactoserum protein hydrolyzate and lactose, and then removing the bacteria and extracting a specific fraction (exclusion fraction obtained from a gel exclusion chromatography having an exclusion threshold of 66 kDA) of the aqueous substrate obtained after incubation.

In the present rejections, the Examiner asserts that because Blareau discloses the same bacterial strain, the strain inherently includes at least one peptide corresponding to DEQ. ID. NOs: 1, 2, and 3. Applicants respectfully disagree with this assertion. Indeed, peptide corresponding to SEQ. ID. NOs: 1, 2, and 3 (contained in the immunomodulatory product according to the claimed invention) are obtained after the removal of *Bifidobacterium breve* I-

2219 from the aqueous substrate; as such, these peptides are present in the substrate and not in the strain.

Further it is apparent from US 2008/0268099 that the method described in Blareau uses a different substrate than the method of the claimed invention. Since the substrates for culturing US 2008/0268099 are different, the obtained immunomodulatory products are also necessarily different.

Example 2 of the present application shows the major influence of the substrate's composition on the composition of the obtained fraction: in this example, the composition of two immunomodulatory products according to the claimed invention (E1 and E2) are compared with a fraction (ML) obtained after cultivating *Bifidobacterium breve* I-2219 on a lactose medium (the other conditions are in accordance with those of the claimed invention). Table I clearly shows important differences in sugars composition in the ML fraction compared to the E1 and E2 fractions. Accordingly, this example experimentally confirms that the composition of the substrate on which the *Bifidobacterium breve* I-2219 is cultured has a significant influence on the composition of the product obtained after culturing *Bifidobacterium breve* I-2219.

Additionally, the claimed immunomodulatory product is further distinguished from the product of Blareau by (i) removal of the *Bifidobacterium breve* I-2219; and (ii) the extraction of a specific fraction after exclusion gel exclusion chromatography having exclusion threshold of 600 kDa.

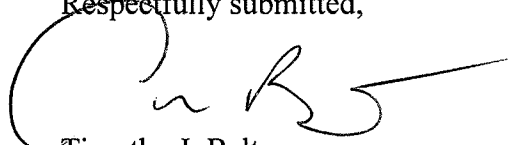
This last step in the extraction leads to a concentrated immunomodulatory product. As a consequence, the product obtained in accordance with Blareau has a different composition and is less concentrated than the immunomodulatory product of the claimed invention. As such, it is readily apparent that Blareau does not disclose or suggest the claimed invention. The teachings of US 7,410,653 and WO 01/01785 are the same as US 2008/0268099, and therefore the claimed invention is patentable over these references for the same reasons given above.

In view of the foregoing amendments and remarks, it is respectfully submitted that the rejections under 35 U.S.C. § 102, 103, and 112 have been overcome, and that the pending claims are in condition for immediate allowance.

Appl. No.: 10/552,957
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It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Timothy J. Balts', with a long horizontal stroke extending to the right.

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